K082200

NOV 25 2008

PREMARKED NOTIFICATION
[510 (K)] SUMMARY

1. IDENTIFICATION

2. DEVICE NAME

3. PREDICATE DEVICE

4. DESCRIPTION

5. INTENDED USE

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

1. IDENTIFICATION

- *Denomination:* **KLOCKNER dental implants**

- *Manufacturer name and address:* **SOADCO, S.L.**
Avgda. Fiter i Rossell, 4bis – Local 2
ESCALDES - ENGORDANY
AD-700 (ANDORRA)

- *Contact person:* **Maria Mitjaneta**

- *Telephone and Fax numbers:* **(376) 800 590** / Fax- **(376) 800 594**

- *Date:* **07/29/08**

2. DEVICE NAME

TRADE NAME: KLOCKNER essential dental implants system model Essential Cone 1.5

COMMON NAME: Dental endosseous implant

CLASSIFICATION NAME: Endosseous implant (21 CFR 872.3640)

3. PREDICATE DEVICE / LEGALLY MARKETED DEVICE

NAME: Dental endosseous implant

LEGALLY MARKETED DEVICE:
Klockner dental implants model Essential Cone (K080224)

4. DESCRIPTION

The Klockner Essential Cone 1.5 implant system consists of a implants to restore the mastication system. The different EC 1.5 are available in four different diameters: 3.5mm, 4.0mm, 4.5mm and 4.8mm and the range of lengths varies between 8mm and 16mm. They are internally connected.

5. INTENDED USE OF THE DEVICE

The Klockner Essential implant system is especially designed for surgical insertion into the bone to replace the root of the teeth, acting as the support for the dental implants formed by implant accessories.

The Essential Cone 1.5 implants are fitted with an internal octagonal conical connection.

Immediate loading is appropriate for the Essential Cone 1.5 implants when good primary stability is achieved with appropriate occlusal loading.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The subject implants are substantially equivalent to the previously cleared Klockner Essential Cone (EC) dental implants system cleared in K080224 because the intended use, the composition and the endosseous surface treatment are identical to the Klockner Essential predicate devices. The design principles are the same as the Klockner Essential predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Maria Mitjaneta
Quality Assurance Manager
SOADCO, S.L.
Avgda Fiter I Rossell, 4 Bis Local 2
Escaldes-Engordany
Andorra AD-700

Re: K082200
Trade/Device Name: Klockner Essential Implant System Models Essential Cone 1.5
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: November 10, 2008
Received: November 12, 2008

Dear Ms. Mitjaneta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K082200

Device Name: KLOCKNER ESSENTIAL IMPLANT SYSTEM MODELS ESSENTIAL CONE 1.5

Indications For Use:

The Klockner Essential implant system is especially designed for surgical insertion into the bone to replace the root of the teeth, acting as the support for the dental implants formed by implant accessories.
The Essential Cone 1.5 implants are fitted with an internal octagonal conical connection.
Immediate loading is appropriate for the Essential Cone 1.5 implants when good primary stability is achieved with appropriate occlusal loading.
8mm Implants are not indicated for use as single implants and for immediate load.

Prescription Use (Per 21 CFR 801.109)	X	**OR**	**Over-The-Counter Use**

R&Botz DDS for Dr. Susan Reuner

ision Sign-Off)
sion of Anesthesiology, General Hospital
tion Control, Dental Devices

510(k) Number: K082200